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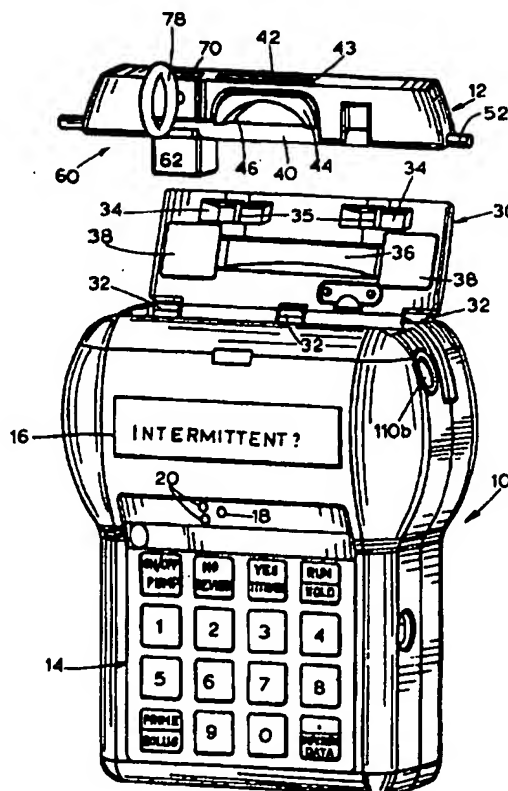
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US96/03002 (22) International Filing Date: 5 March 1996 (05.03.96) (30) Priority Data: 08/398,886 6 March 1995 (06.03.95) US (71) Applicant: SABRATEK CORPORATION [US/US]; 5601 W. Howard, Niles, IL 60714 (US). (72) Inventors: HYMAN, Oscar; Unit F, 222 Vine Avenue, Park Ridge, IL 60068 (US). PRIBIL, Jeffery; 1385 Springhill Drive, Algonquin, IL 60102 (US). DECKERT, Clinton; 15518 Marker Drive, Poway, CA 92064 (US). KALO, Aric; 16 Hashiryon Street, 70400 Nes-Ziona (IL). (74) Agent: HIRSCH, Martin; Marshall, O'Toole, Gerstein, Murray & Borun, 6300 Sears Tower, 233 South Wacker Drive, Chicago, IL 60606-6402 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: CASSETTE FOR AN INFUSION PUMP (57) Abstract <p>A cassette (12) which is adapted to be insertable into and removable from an infusion pump (10). The cassette (12) has a housing, a length of flexible tubing (40) supported by the housing, and a vertically movable member (64) disposed in the housing. The movable member (64) has a slot formed therein, and a portion of the flexible tubing (40) is disposed within the slot. The member (64) is movable between a clamped position in which the flexible tubing (40) is clamped to prevent any substantial liquid flow therethrough and an unclamped position in which substantial liquid flow through the flexible tubing (40) is enabled, and a spring is provided for biasing the member (64) to the clamped position. The movable member (64) may be designed so that the closure of a door of the infusion pump (10) in which the cassette is inserted will cause the member (64) to be in the unclamped position to allow liquid flow through the flexible tubing (40). The cassette (12) may have means for maintaining the member (64) in the unclamped position, such as a retaining pin. The cassette (12) has a second vertically movable member (44) with a first surface (46) and a second surface (42). The first surface (46) has a portion which is arcuate in shape and adapted to substantially conform with a path of rotation defined by the rotary pump wheel of the infusion pump (10). The second surface (42) of the second movable member (44) is disposed within the aperture formed in the upper surface of the housing so that the second member (44) may be vertically displaced due to physical contact with the second surface (42) of the member (44).</p>		



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- 1 -

CASSETTE FOR AN INFUSION PUMP**Background of the Invention**

The present invention is directed to a cassette for an
5 infusion pump which may be inserted into and removed from the
pump.

An infusion pump is used to automatically administer
liquid medicant to a patient. The liquid medicant is supplied
from a source of medicant and pumped into the patient via a
10 catheter or other injection device. The manner in which the
liquid is infused is controlled by the infusion pump, which may
have various modes of infusion, such as a continuous mode in
which the liquid medicant is continuously infused at a constant
rate, or a ramp mode in which the rate of infusion gradually
15 increases, then remains constant, and then gradually decreases.

Some infusion pumps utilize a cassette or module which may
be inserted into and removed from the pump. One such module
is disclosed in U.S. Patent No. 5,257,978 to Haber, et al. The
module 2 disclosed in that patent receives a length of an
20 intravenous line 4 in its interior, and a length of silicon
tubing 78 is connected to the intravenous line 4 to form a
single continuous conduit. The module 2 is insertable into an
infusion pump, in the form of a peristaltic pump 5, via a door
80 which may be opened and closed. The pump 5 is constructed
25 so that it will operate only when the door is completely
closed.

Summary of the Invention

The invention is directed to a cassette which is adapted
30 to be insertable into and removable from an infusion pump. In
one aspect, the invention is directed to a cassette having a
housing, a length of flexible tubing supported by the housing,
and a vertically movable member disposed in the housing. The
vertically movable member has a slot formed therein, and a
35 portion of the flexible tubing is disposed within the slot.
The vertically movable member is movable between a clamped
position in which the flexible tubing is clamped to prevent any

- 2 -

substantial liquid flow therethrough and an unclamped position in which substantial liquid flow through the flexible tubing is enabled, and a spring is provided for biasing the vertically movable member to the clamped position.

5 The housing may have an upper surface with an aperture formed therein, and the vertically movable member may have an upper portion which extends through the aperture to an elevation higher than the upper surface of the housing when the vertically movable member is disposed in the clamped position,
10 so that the closure of a door of an infusion pump in which the cassette is inserted will cause the vertically movable member to be in the unclamped position to allow liquid flow through the flexible tubing.

 The cassette may have means for maintaining the vertically
15 movable member in the unclamped position, such as a retaining pin. The retaining pin may be insertable in a first bore formed in the vertically movable member and a second bore formed in the housing. The cassette housing may be provided as a compact housing having a length, a width, and a height,
20 wherein the length of the housing is about six times the height of the housing, and wherein the height of the housing is about twice the width of the housing.

 In another aspect, the invention is directed to a cassette adapted to be insertable into an infusion pump having a rotary
25 pump wheel and removable from the infusion pump. The cassette in accordance with this aspect has a housing with a length, a width, and a height and an upper surface with an aperture formed therein. The length of the housing is at least about five times the height of the housing, and the height of the
30 housing is at least about twice the width of the housing. A length of flexible tubing is supported by the housing.

 The cassette has a vertically movable member with a first surface and a second surface. The first surface has a portion which is arcuate in shape and adapted to substantially conform
35 with a path of rotation defined by the rotary pump wheel of the infusion pump. The second surface of the vertically movable member is disposed within the aperture formed in the upper

- 3 -

surface of the housing so that the vertically movable member may be vertically displaced due to physical contact with the second surface of the vertically movable member.

These and other features and advantages of the present invention will be apparent to those of ordinary skill in the art in view of the detailed description of the preferred embodiment, which is made with reference to the drawings, a brief description of which is provided below.

10 Brief Description of the Drawings

Fig. 1 is a perspective view of an ambulatory infusion pump and a first type of cassette which is insertable into the pump;

15 Fig. 2A is a cross-sectional front view of a portion of the infusion pump of Fig. 1 with the cassette disposed therein;

Fig. 2B is a cross-sectional side view of a portion of the infusion pump of Fig. 1 with the cassette disposed therein;

20 Fig. 3A is a cross-sectional front view of a portion of the infusion pump of Fig. 1 with a second type of cassette disposed therein;

Fig. 3B is a cross-sectional side view of a portion of the infusion pump of Fig. 1 with the second type of cassette disposed therein;

25 Fig. 4A is a cross-sectional side view of the first type of cassette in which a flexible tube is clamped;

Fig. 4B is a top view of the cassette of Fig. 4A;

Fig. 5A is a front elevational view of a platen which forms part of the cassette of Fig. 4A;

30 Fig. 5B is a side elevational view of the platen of Fig. 5A; and

Fig. 6 is cross-sectional side view of a portion of the infusion pump.

35 Detailed Description of a Preferred Embodiment

A preferred embodiment of a battery-powered, ambulatory infusion pump 10 in accordance with the invention is illustrated in Fig. 1 along with a first type of cassette 12

- 4 -

which is insertable into the pump 10. The portable pump 10 may be carried in a pouch or other device (not shown) attached to a patient so that the pump 10 may be carried wherever the patient goes.

5 The infusion pump 10 has a keypad 14 via which a user may input data and commands, a selectively backlighted, dot matrix display 16 for displaying textual messages to the user, a light sensor 18 for detecting the level of ambient light, and a pair of light-emitting diodes (LED) 20, a green LED for indicating
10 the normal operation of the pump 10 and a red LED for indicating an alarm or abnormal operating condition of the pump 10.

 A door 30 is pivotally attached to the upper portion of the infusion pump 10 via a number of hinges 32. The underside
15 of the door 30, which is shown in Fig. 1, has a pair of slots formed therein in which a pair of metal rods 35 are fixed. As described below, each of the metal rods 35 selectively engages a pair of slidable latching members to retain the door 30 in the closed position during operation of the pump 10.

20 An arcuate metal leaf spring 36 is disposed on the underside of the door 30. The two ends of the leaf spring 36 are anchored by a pair of retaining elements 38 fixed to the door 30. When the cassette 12, in which a flexible silicon tube 40 is disposed, is inserted into the pump 10 and the door
25 30 is closed, the leaf spring 36 makes contact with and applies a downward force on the upper surface 42 of a vertically movable platen 44. As shown in Figs. 1 and 4B, the upper surface 42 of the platen 44 is disposed within an elongated slot or aperture 43 disposed in the upper surface of the
30 cassette housing 12. The platen 44 has a lower curved surface 46 against which the flexible tube 40 is pressed by a number of rollers 48 disposed on a conventional rotary pump wheel 49 (see Fig. 2A) to facilitate pumping of liquid through the tube 40. The rotary pump wheel 49 is fixed to a gear 50 (Fig. 2B)
35 which is driven by a drive belt (not shown) connected to a DC motor via a gear drive assembly (not shown).

- 5 -

Liquid is supplied to the tube 40 via a supply tube 52 connected to a source of liquid, which may be a liquid supply container or bag (not shown) fixed to the housing of the pump 10. The liquid is infused into the patient via a catheter or other injection device (not shown) fluidly connected to a length of tubing 54 fluidly connected to the tube 40. The tubing 52, 54 may comprise conventional polyvinylchloride (PVC) tubing having an outside diameter slightly larger than the inside diameter of the flexible tube 40 so that the tubing 52, 54 may be inserted into the flexible tube 40 to effect a liquid-tight seal.

The tubing 52, 54 may be solvent-bonded to the cassette housing 12, which is plastic, to prevent the tubing 52, 54 from being inadvertently pulled from the tube 40. As shown in Fig. 4A, the bottom portion of the cassette 12 has two semi-circular retaining members 56 integrally formed therewith, each of which abuts a portion of the flexible tube 40 where it overlaps the tubing 52, 54 to further prevent the tubing 52, 54 from being inadvertently pulled from the tube 40. A second pair of similar semi-circular retaining members are integrally formed with the pump housing at a point directly below the retaining members 56, as shown in Figs. 2A and 3A, for the same purpose.

The cassette 12 has a flow-stop mechanism 60 that automatically clamps the flexible tube 40 shut when the cassette 12 is not disposed in the pump 10 or when the pump door 30 is open. The flow-stop mechanism 60, which is shown in detail in Figs. 2A and 2B, has a housing 62 in which a vertically displaceable flow-stop member 64 and a spring 66 are disposed. As shown in Fig. 2B, the flexible tube 40 passes through a slot 68 formed in the flow-stop member 64, and the spring 66 biases the flow-stop member 64 upwardly.

While the cassette 12 is disposed in the pump 10 with the door 30 closed, one of the spring retaining members 38 makes contact with an upper surface 70 of the flow-stop member 64, thus preventing the spring 66 from forcing the flow-stop member 64 upwards enough to cause the flexible tube 40 to be flattened by the bottom surface of the slot 68. When the door 30 is

- 6 -

opened, or when the cassette 12 is not disposed within the pump 10, the spring 66 forces the flow-stop member 64 upwards a distance sufficient to flatten the flexible tube 40, as shown in Fig. 4A, so as to prevent any liquid flow therethrough.

5 When the cassette 12 is in the pump 10, as the pump door 30 is closed, one of the rollers 48 of the rotary pump wheel 49 will make contact with the flexible tube 40, causing it to be clamped shut, as shown in Figs. 2A and 3A, and then subsequently, as the door 30 closes further, the flow stop member 64 will be forced downwards, unclamping the flexible tube 40. Thus, the tube 40 will be clamped at all times, either by one of the rollers 48 or by the flow stop member 64. Similarly, as the door 30 is opened, the flow stop member 64 will clamp the flexible tube 40 before the roller(s) 48 of the rotary pump wheel 49 unclamp the tube 40, thus preventing any liquid free-flow through the tube 40.

10 When the cassette 12 is not inserted into the pump 10, the flow-stop mechanism 60 may be disabled by manually aligning a bore 74 (Fig. 2B) in the flow-stop housing 62 with a bore 76 in the flow-stop member 64 and inserting a pin 78 (see Fig. 1) into the aligned bores 74, 76. When placed in the bores 74, 76, the pin 78 will prevent the flow-stop member 64 from being displaced upwardly by the spring 66, and thus prevent the flexible tube 44 from being flattened and the liquid flow from being cut off.

25 Figs. 3A and 3B illustrate a second type of cassette, which is shown disposed within the infusion pump 10. The only difference between the two types of cassettes 12 is the size and shape of the bottom portion of the flow-stop member 64. The bottom portion of the flow-stop member 64 of the first type of cassette 12, shown in Figs. 2A and 2B, is generally spherical and does not extend outside of the flow-stop housing 62. The bottom portion of the flow-stop member 64 of the second type of cassette 12, shown in Figs. 3A and 3B, has a downwardly angled finger 82 that extends through a circular bore 84 disposed in the bottom of the flow-stop housing 62.

- 7 -

Referring to Figs. 4A and 4B, the cassette 12 has a length L of approximately 9.7 centimeters (cm), a height H of approximately 1.5 cm, and a width W of approximately 0.8 cm. The outer diameter of the flexible tube 40 (when undistorted) is approximately 0.4 cm.

The upper surface 42 of the platen 44, which is shown in Figs. 4A and 4B, has an elongated central aperture 86 formed therein and is slightly curved to generally conform to the arcuate shape of the leaf spring 36. As shown in Figs. 5A and 5B, the platen 44 has a bottom portion 90 and a top portion 92, the bottom portion 90 being wider than the top portion 92. The top portion 92 of the platen 44 is loosely disposed within the slot 43 (Fig. 4B) formed in the cassette 12 and is retained in the slot 43 only by the presence of the flexible tube 40 beneath the bottom of the platen 44, as shown in Fig. 4A.

The infusion pump 10 has a latching mechanism 100, illustrated in Fig. 6, for retaining the door 30 in its closed position. Referring to Fig. 6, the latching mechanism 100 includes a pair of horizontally slidable metal plates 102a, 102b which are supported by a flat portion of a rotary pump wheel housing 104 and a pair of support beams 106. Each of the metal plates 102a, 102b has a respective pair of curved latch members 108a, 108b integrally formed therewith. A pair of independently operable door-release buttons 110a, 110b are disposed on either side of the infusion pump 10. Each door-release button 110a, 110b has a hollow cylindrical body portion 112a, 112b and a central member 114a, 114b disposed within the hollow body portion 112a, 112b. Each of the central members 114a, 114b engages a respective end of one of the slidable plates 102a, 102b. A pair of annular slots 116a, 116b are formed in the body portions 112a, 112b, and a pair of ridges 118a, 118b integrally formed with the pump housing are disposed within the slots 116a, 116b to limit the horizontal displacement of the door-release buttons 110a, 110b.

Each of the slidable plates 102a, 102b has a respective central aperture 120a, 120b disposed therein, and a spring 122 is disposed within both the of central apertures 120a, 120b so

- 8 -

as to spring-bias or force each of the slidable plates 102a, 102b against the central member 114a, 114b of the door-release button 110a, 110b with which the end of the slidable plate 102a, 102b makes contact. The spring 122 may be retained
5 within the apertures 120a, 120b by an L-shaped retaining member (not shown).

As shown in Fig. 6, the two curved latches 108a, 108b of each of the plates 102a, 102b engage both of the rods 35 fixed to the underside of the pump door 30, due to the force of the
10 spring 122, thus preventing the door 30 from being opened. Each plate 102a, 102b alone is sufficient to keep the door 30 closed. To open the door 30, both of the door-release buttons 110a, 110b must be simultaneously depressed, in which case the slidable plates 102a, 102b are moved, against the force of the
15 spring 122, to cause the curved latches 108a, 108b to disengage the metal rods 35, thus allowing the door 30 to be opened. The door 30 may be provided with a spring or other means (not shown) to cause the door 30 to open automatically when both of the door-release buttons 110a, 110b are pressed. Since both
20 of the door-release buttons 110a, 110b must be actuated to open the door 30, any inadvertent opening of the door 30 due to the infusion pump 10 being dropped or jarred is reduced or eliminated.

- 9 -

WHAT IS CLAIMED IS:

1. A cassette (12) adapted to be insertable into an infusion pump (10) having a rotary pump wheel (49) and removable from said infusion pump (10), said cassette (12) having a housing with a length, a width, and a height, said cassette (12) characterized by having a length of flexible tubing (40) supported by said housing, said housing having an upper surface with an aperture (43) formed therein, further characterized by a vertically movable member (44) having a first surface (46) and a second surface (42), said first surface (46) having a portion which is arcuate in shape and adapted to substantially conform with a path of rotation defined by said rotary pump wheel (49) of said infusion pump, said second surface (42) being disposed within said aperture (43) formed in said upper surface of said housing so that said vertically movable member (44) may be vertically displaced due to physical contact with said second surface (42) of said vertically movable member (44).

20

2. A cassette as defined in claim 1 wherein said length of said housing is at least about five times said height of said housing and said height of said housing is at least about twice said width of said housing.

25

3. A cassette as defined in claim 1 further characterized by a second vertically movable member (64) disposed in said housing, said second vertically movable member (64) having a slot (68) formed therein, a portion of said flexible tubing (40) being disposed within said slot (68), said second vertically movable member (64) being movable between a clamped position in which said flexible tubing (40) is clamped to prevent any substantial liquid flow therethrough and an unclamped position in which substantial liquid flow through said flexible tubing (40) is enabled.

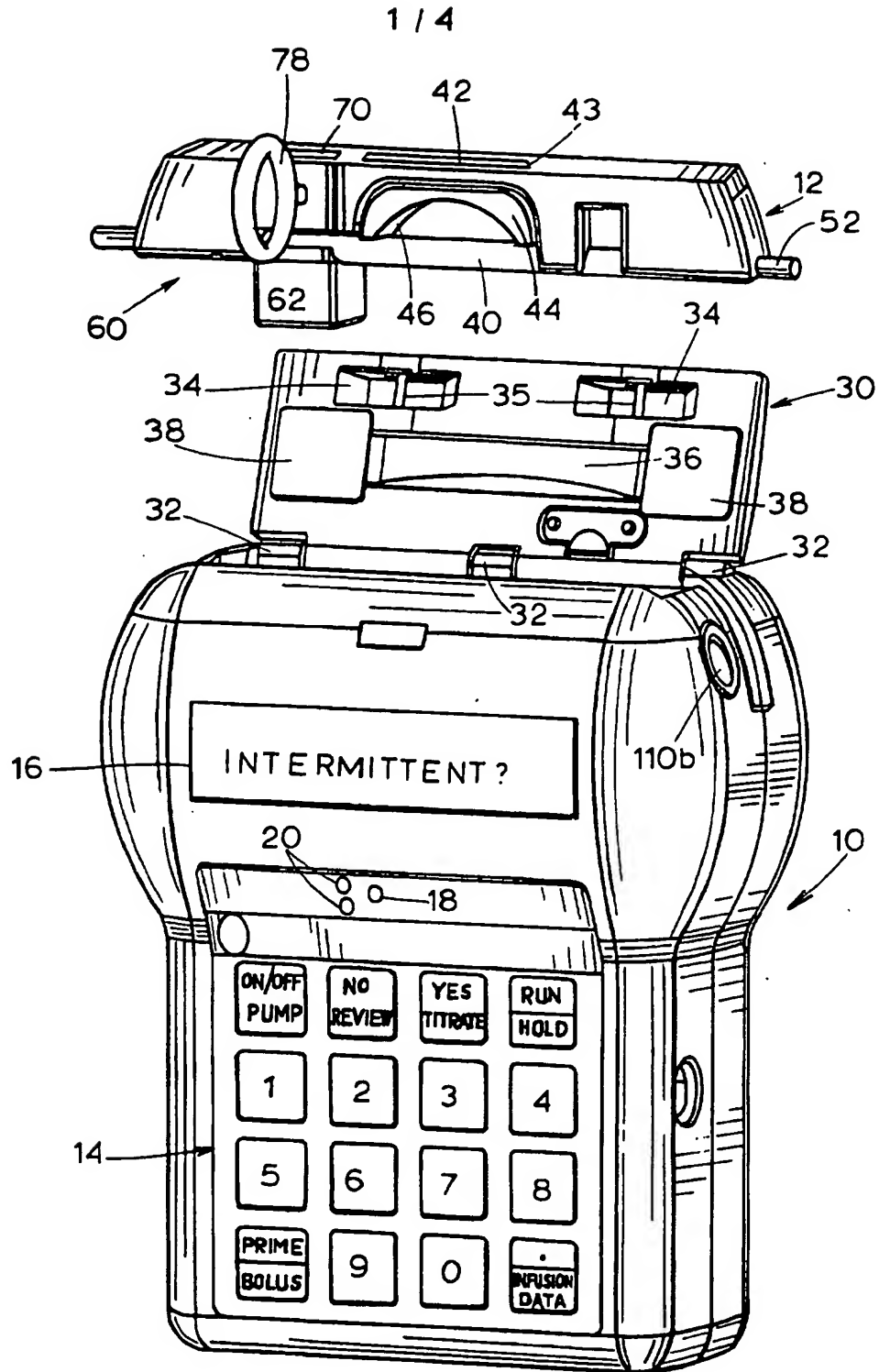
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- 10 -

4. A cassette as defined in claim 3 wherein said upper surface of said housing has a second aperture formed therein and wherein said second vertically movable member (64) has an upper portion which extends through said second aperture to an elevation higher than said upper surface of said housing when said second vertically movable member (64) is disposed in said clamped position.

5. A cassette as defined in claim 3 further characterized by means for maintaining said second vertically movable member (64) in said unclamped position.

6. A cassette as defined in claim 3 wherein said second vertically movable member (64) has a first bore formed (76) therein and where said housing has a second bore (74) formed therein, said cassette additionally comprising a pin (78) which is insertable through said first and second bores (74, 76) to maintain said second vertically movable member (64) in said unclamped position.

**Fig. 1**

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2 / 4

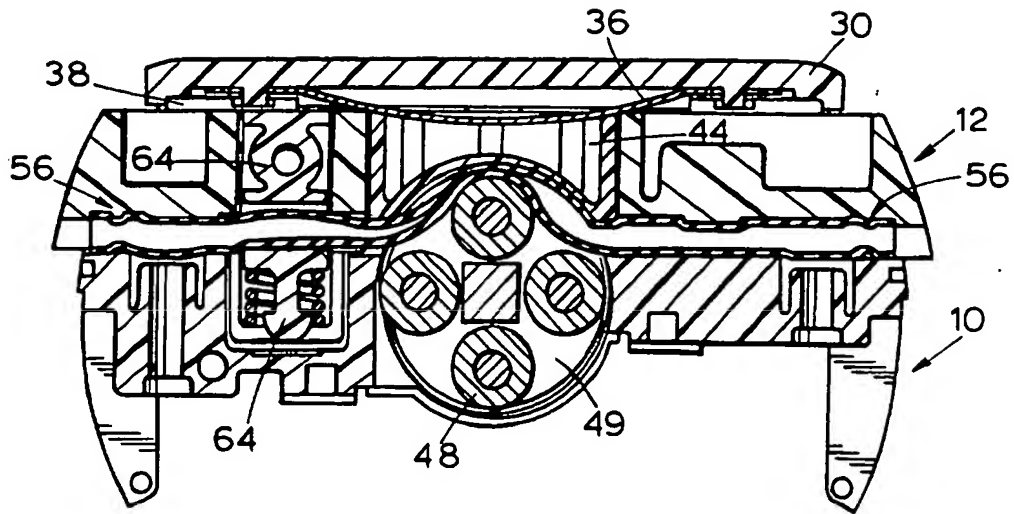


Fig. 2a

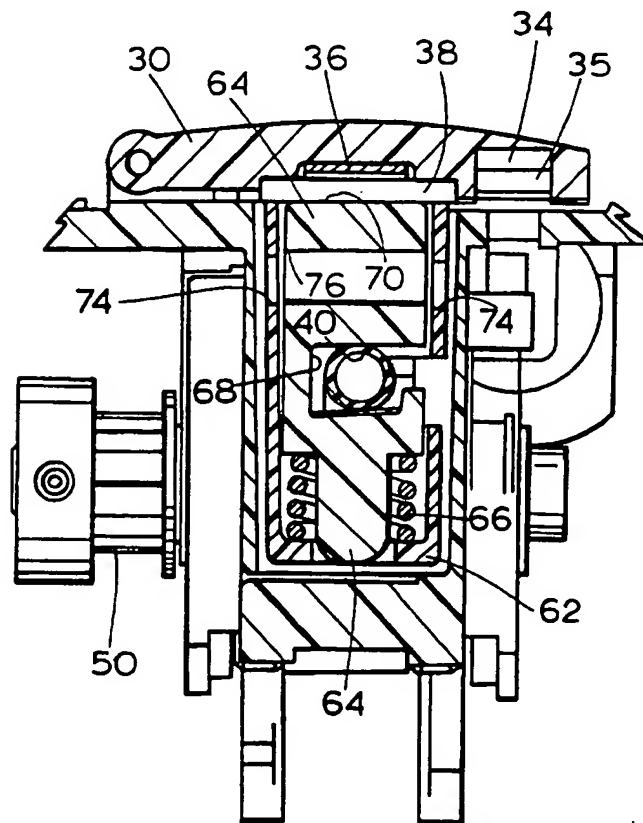


Fig. 2b

3 / 4

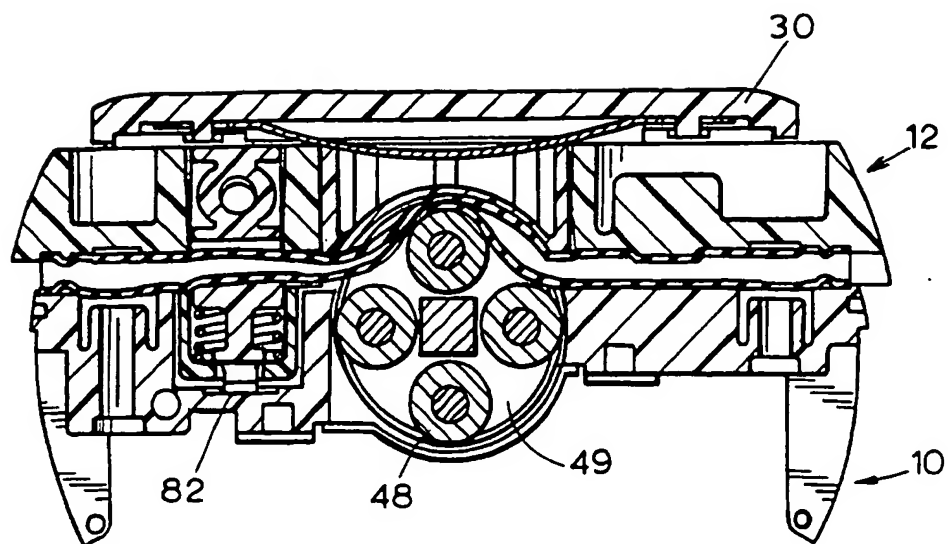


Fig. 3a

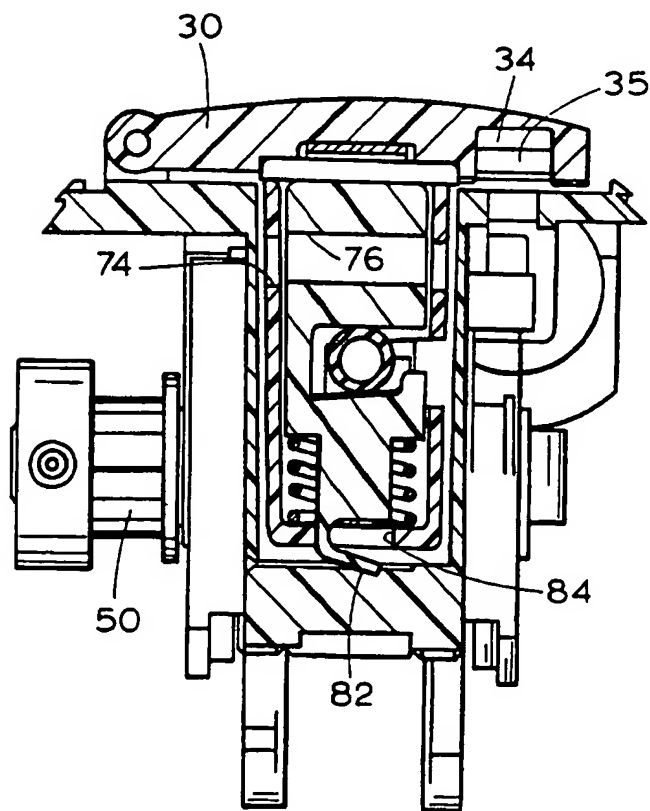


Fig. 3b

4 / 4

Fig. 4a

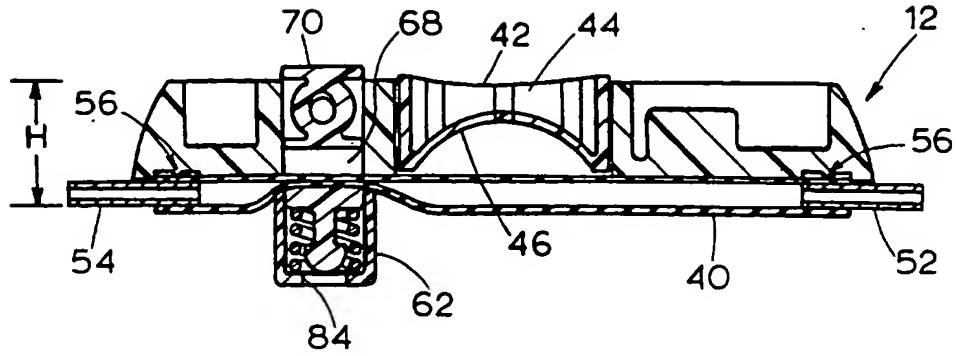


Fig. 4b

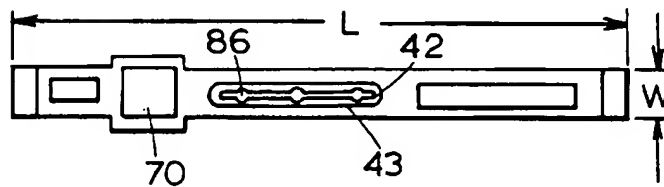


Fig. 5b

Fig. 5a

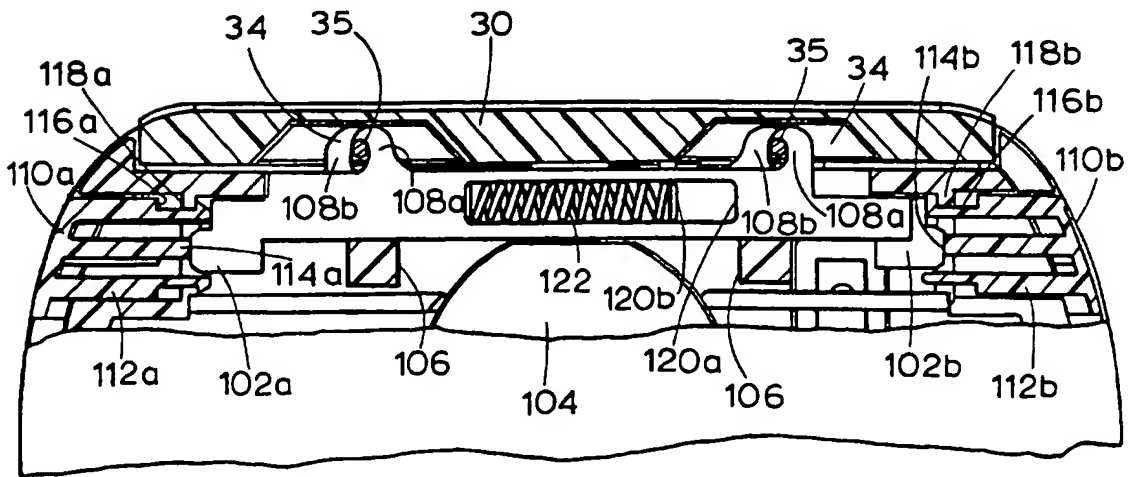
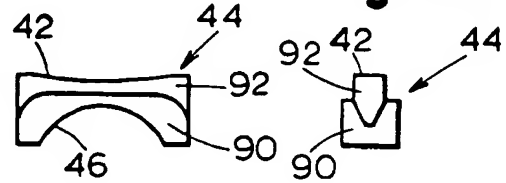


Fig. 6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/03002

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/142 F04B43/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M F04B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,5 213 483 (FLAHERTY ET AL.) 25 May 1993 see column 6, line 19 - line 68 see figures 1,4 ---	1,2
X	DE,A,40 27 188 (CSIR) 7 March 1991 see column 4, line 36 - column 6, line 50 see figures 3-5 ---	1,2
A	FR,A,2 336 571 (MILES LABORATORIES) 22 July 1977 see page 5, line 25 - page 9, line 18 see figures 1-4 -----	1-3,5

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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